

**REMARKS**

Applicants would like to thank Examiner Myers for the courtesy extended during the telephone discussion of December 14, 2005 regarding the outstanding Office Action, and the further telephone discussions of May 2nd and May 9th regarding the claim rejections and proposed claims.

Claims are presented in view of the Advisory Action which indicates that the proposed amendments were not entered. Claims 50, 61, 65-68, and 76-80 would be pending in this application after entry of the instant submission. Claims 1-49, 51-60, 62-64, and 69-75 have been cancelled without waiver, solely in order to further prosecution. Applicants reserve the right to prosecute the subject matter of any of the cancelled claims in one or more related applications. Claims 76-80 have been added and claims 61 and 65-67 have been amended. Support for the new and amended claims may be found in the specification. Thus, the new and amended claims are fully supported by the instant specification and no new matter has been introduced.

Applicants acknowledge that claims 50, 61, 65, and 76 would be allowable as indicated in the prior Advisory Action.

**Statement Of The Substance Of The Interview**

The participants in the interview held on December 14, 2005 were the Examiner, Carla Myers, and Applicants' representative, Melissa Wenk.

The Interview Summary mailed by the PTO on January 13, 2006 indicates that claims 50, 63, and 65 were discussed. Applicants' representative also recalls discussing issues raised by the Office Action and pending claims.

As reflected in the Interview Summary, the Examiner and the Applicants' representative discussed the new matter rejection with respect to the nucleotide sequence of SEQ ID NO:89. Moreover, the written description requirement in view of the SEQ ID NO:89 nucleotide sequence was discussed. Agreement was not reached, and in order to

expedite prosecution of the instant application, Applicants cancelled claims 51-60, 70-73, and 75 in the December 22, 2005 Amendment Under 37 C.F.R. §1.116.

As further reflected in the Interview Summary mailed by the PTO, upon pointing out to the Examiner that a Preliminary Amendment filed March 4, 2005 in divisional application serial no. 11/073,203 cancelled claims 1-13, 29-35 and 43, the Examiner agreed to withdraw the obviousness-type double-patenting rejection.

Furthermore, as reflected in the same Interview Summary as discussed above, the Examiner agreed that claim 50 would be allowable since the prior art did not teach the intron sequences.

#### **Double Patenting Rejection**

Applicants acknowledge the Examiner's withdrawal of the obviousness-type double patenting rejection of claims 44-75 in view of cancelled claims 1-13, 29-35 and 43 of co-pending application serial no. 11/073,203.

#### **Priority**

The Examiner contends that claims 77 and 78 of the previous Response are not entitled to claim priority to Application No. 60/260,080. Applicants respectfully disagree. However, solely in order to further prosecution, Applicants have rewritten the claims to refer to a specific region of the *IKBKAP* gene.

New claims 77 and 79 as presented herein refer to a region from the beginning of exon 19 through exon 20 of the *IKBKAP* gene of SEQ ID NO:1. The specification and provisional application identify the minor mutation located in a region spanning from the beginning of exon 19 and exon 20. This region is disclosed in multiple ways, *i.e.*, from the description, figures, and sequences. One skilled in the art would recognize the relevance and importance of this region as opposed to the other regions of the *IKBKAP* gene. Each of these bases for support of the claims was disclosed in the provisional application. The region

beginning from exon 19 through exon 20 of the *IKBKAP* gene of SEQ ID NO: 1 is exemplified in the schematic of Figure 1 which shows both intron and exon regions and their approximate location in the *IKBKAP* gene sequence. Figure 1 also identifies with asterisks that the minor mutation is in this region of the gene. Figure 6 of the provisional application (USSN: 60/260,080) shows the genomic *IKBKAP* sequence of SEQ ID NO:1 which includes a region extending from the beginning of base pair 33,642 through 34,195 corresponding to the region beginning from exon 19 through exon 20. One skilled in the art would understand that this region may be determined by reading the sequencing gel of Figure 2C which provides the sequence boundary between exon 19 and exon 20 and cDNA sequence provided in Accession No. AF153419 in conjunction with the genomic sequence of Figure 6, and as described in the instant specification.

Similarly, claims 66-67 are directed to a kit for identifying mutations disclosed in the paragraph above, Figure 1, Figure 6, and throughout the instant specification. The specific primers that are used to amplify a region extending from the beginning of exon 18/19 through exon 23 of the *IKBKAP* gene sequence of SEQ ID NO:1. Support may be found throughout the specification, including Figure 1 which shows the primers and locations with respect to the intron and exon regions of the *IKBKAP* gene. Therefore, claims 66-67 similarly have support as disclosed in the provisional application.

Claims 78 and 80 are directed to the coding sequence of SEQ ID NO:2. In the provisional application, the sequence of Accession No. AF153419 was stated at pages 9 and 11. Subsequent to the filing of the provisional application, the sequence submitted under Accession No. AF153419 was revised at the non-coding 3' end, but one skilled in the art would recognize that the region of interest is limited to the coding sequence which was not altered. In fact, the only portion of the sequence which would be used by one skilled in the art in the context of the claimed invention is not changed, *i.e.*, the coding region.

As such, applicants contend that the currently pending claims are entitled to the date of the provisional application obviating any grounds of rejection based on intervening publications. Reconsideration and withdrawal of all rejections directed to the pending claims are respectfully requested.

**Specification**

The Examiner contends that new matter has been added to the specification by the introduction of SEQ ID NO:89 to the Substitute Sequence Listing filed on September 8, 2005. Applicants respectfully disagree. However, solely in order to further prosecution, a new Substitute Sequence Listing was submitted in the prior response omitting SEQ ID NO:89. Because the computer readable format (CRF) was found to be unreadable, applicants submit herewith another CRF of the Substitute Sequence Listing (1 diskette), a paper copy of the Substitute Sequence Listing, and a Statement indicating that the CRF and paper copy of the Substitute Sequence Listing are the same. Applicants respectfully request that the rejection be withdrawn.

**CONCLUSION**

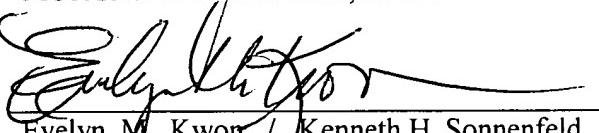
Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Withdrawal of the Examiner's rejections and a notice of allowance are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

**AUTHORIZATION**

No fee is believed to be due. However, the Commissioner is hereby authorized to charge any fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 1829-4004US1.

Respectfully submitted,

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